K000076

MAR - 3 2000

510(k) Summary of Safety and Effectiveness

510(k) Submitter:	Streck Laboratories, Inc. P.O. Box 45625 Omaha, NE 68145-0625
Official Correspondent:	Paul Kittelson Quality Assurance/Regulatory Affairs (402) 691- 7465
Date Prepared:	January 4, 2000
Names of Device:	
Trade Name:	Cell-Chex
Common Name:	Assayed cell control
Classification Name:	White and Red Blood Cell Control
Predicate Device:	Spinalscopics (K970862) manufactured by Quantimetrix Corporation.

Description: Cell-Chex is a suspension of stabilized red blood cells and white blood cells derived from human sources. They are preserved to simulate the cells typically found in body fluids in morphology and count. The product is packaged in glass vials containing 3.0 ml. The closures are polypropylene screw caps with polyethylene liners.

Intended Use: Cell-Chex is intended for use as a control to monitor manual cell counting procedures used for determining the WBC and RBC counts in body fluids such as cerebrospinal fluid.

Comparison with Predicate Device:

Cell-Chex is similar to Quantimetrix' Spinalscopics product since it consists of stabilized RBC and WBC components at concentrations typical of body fluids. The packaging for both contain two control levels that simulate a low cell count and a higher (abnormal) count. Both products are intended to be used in controlling manual body fluid cell count procedures.

Cell-Chex differs from Spinalscopics by the type of WBC component employed. Human derived WBC are stabilized by a procedure that retains their morphological and staining properties. The benefit to the user is the ability to perform a WBC differential count

Testing Performed:

Four types of studies were conducted to establish performance of Cell Chex. a.) Long term stability (Shelf Life), b.) Open vial stability, c.) Site to Site recovery of values, d.) "With-in Run" precision studies and comparison to predicate product. All testing showed that Cell Chex is consistently reproducible, substantially equivalent to the predicate product and stable for the shelf life claimed.

Conclusions Drawn from the Tests:

Cell-Chex is a safe and effective product useful for controlling the manual cell counting procedures employed in body fluid cell analysis. It will perform as claimed when used in accordance with the package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 3 2000

Mr. Paul Kittelson
Quality Assurance/Regulatory Affairs
Streck Laboratories, Inc.
14124 Industrial Road
Omaha, Nebraska 68144

Re: K000076
Trade Name: Cell-Chex
Regulatory Class: II
Product Code: GJR
Dated: January 4, 2000
Received: January 10, 2000

Dear Mr. Kittelson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

January 7, 2000

510(k) Number (if known): K000076

Device Name: Cell-Chex

Indications for Use:

Body fluid cell counts are usually performed using manual methods employing a hemacytometer and microscope. Quality control procedures for this clinical test typically utilize stabilized cell suspensions. Cell Chex is a suspension of human RBC and WBC with assayed cell counts. The WBC component can be differentiated into mononuclear and polymorphonuclear populations. A laboratory can use this product to monitor the counting performance of laboratory technologists and verify the quality of clinical count results.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000076

Prescription Use ✓ OR **Over-The-Counter Use** __
(Per 21CFR 801.109) (Optional format 1-2-96)